DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 09 2008

BioVision Technologies, LLC
% TÜV SÜD America Inc.
Ms. Dawn Tibodeau
1775 Old Highway 8 NW, Suite 104
New Brighton, Minnesota 55112-1891

Re: K082293
Trade/Device Name: SurgView™ Integrated Visualization System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX, GCJ
Dated: August 22, 2008
Received: August 25, 2008

Dear Ms. Tibodeau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082293

Indications for Use

510(k) Number (if known): K082293

Device Name: SurgView™ Integrated Visualization System

Indications for Use:

The SurgView™ Integrated Visualization System is indicated to be used by a trained physician to provide illumination and visualization of an interior cavity of the body through a natural or surgical opening in diagnostic and operative arthroscopic and endoscopic procedures. Examples of surgical use include but are not limited to procedures on the knee, shoulder, ankle, elbow, wrist, temporomandibular joint (TMJ), spinal, ophthalmic, ENT, and the cervix.

David Krause for MKM

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K082293

Prescription Use ✓ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ✗ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary of Safety and Effectiveness
SurgView™ Integrated Visualization System

Date: June 3, 2008

Applicant/Sponsor: BioVision Technologies, L.L.C.

Address: 221 Corporate Circle Unit H
Golden, Colorado 80401
Telephone Number: (303) 237-9608
Facsimile Number: (303) 237-0757

Contact Person: David Sanso
President

Proprietary Name: SurgView™ Integrated Visualization System

Regulation Name: Arthroscope
Endoscope

Regulation Number: 21 CFR §888.1100, HRX
21 CFR §876.1500, GCJ

Regulatory Class: II

Information on devices to which substantial equivalence is claimed:

COMPANY	DEVICE	510(k)
Biomet Sports Medicine	InnerVue Diagnostic Scope System	K072879
Smith & Nephew	Video Arthroscope	K043395
Arthrex, Inc	Arthrex Arthroscopes	K030096
Medtronic Sofamor Danek	METRx System	K002931
Davlite Technologies	Davlite Microendoscope	K020310

Device Description:
The SurgView™ Integrated Imaging System is a video endoscope/arthroscope imaging system consisting of the following components:

1. A Light Source/Display/Image Capture device that includes a monitor, image processor, Xenon light source, camera unit, and a camera hand piece with integrated fiberoptic cable.

2. A semi-rigid Fiberoptic Scope designed for one time use, in a variety of diameters, lengths, and viewing angles.

3. Supplemental Instruments that can be used interchangeably throughout the procedure. They include a cannula, trocar, obturator, and cannula plug.

4. Procedural Kit that contains a variety of sterile items used to aid in the procedure.

Indications for Use: The SurgView™ Integrated Visualization System is indicated to be used by a trained physician to provide illumination and visualization of an interior cavity of the body through a natural or surgical opening in diagnostic and operative arthroscopic and endoscopic procedures. Examples of surgical use are included but are not limited to procedures on the knee, shoulder, ankle, elbow, wrist, shoulder, temporomandibular joint (TMJ), spinal, ophthalmic, ENT, cervix, and the urethra.

Summary of Technologies: The SurgView™ Integrated Visualization System technological characteristics are similar to predicate devices.

Non-Clinical Testing: Establishment of equivalence is based on similarities of intended use, design, and materials, physical characteristics and geometry between the SurgView™ Integrated Visualization System and predicate devices.

Clinical Testing: Clinical testing was not used to establish substantial equivalence to predicate devices.

Performance and Safety Testing: The SurgView™ Integrated Visualization System complies with UL/CSA/EN60601-1:1990 Medical electrical equipment – Part 1. General requirements for safety; UL/CSA/EN60601-2-18:1996 Medical electrical equipment – Part 2. Particular requirements for the safety of endoscopic equipment; EN60601-1-2, Group 2, Class B. Collateral standard electromagnetic compatibility; 47 CFR Part 15.